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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/723,247	BAR-OR, DAVID	
	Examiner	Art Unit	
	Samuel W. Liu	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46,49-53,81,186,194-199,217-220,246,272,273 and 280-299* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46,49-53,81,186,194-199,217-220,246,272,273 and 280-299* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/20/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 46, 49-53, 81, 186, 194-199, 217-220, 246, 272-273, and 280-299 are pending.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed 11/20/07 has been entered.

The amendment filed 11/20/06, which cancels claims 1-45, 47-48, 54-80, 82-185, 187-193, 200-216, 221-245, 247-271 and 273-279, adds claims 280-299, and amends claims 46, 49, 186, 194-195, 217-220, 272-273 and 280 has been entered. Application request (filed 11/20/06) for extension of time of three months has been entered. New claims 288-299 are drawn to elected invention. Claims 46, 49-53, 81, 186, 194-199, 217-220, 246, 272-273, and 280-299 are thus examined in this Office action.

Priority

Applicant's claim for the benefit of a prior-filed application 60429924 filed 11/27/2002 under 35 U.S.C. 119(e) is acknowledged. However, 60429924 dose not have full support for claims 49 (limitation "chicken phosvitin"), claims 50-53 and 275-280 (limitation "% dephosphorylation"), claims 186-199, 210, 216-228, 239, 241, 245-254, 265, 267 and 271 (limitation "not an aqueous solution or a lyophilized material"), and claims 272-273 (limitation "target molecule attached to"). Thus, these claims are granted priority only to the instant filing date 11/25/03.

IDS

The reference cited in the IDS filed 11/20/07 has been considered by Examiner.

Withdrawal of objections/rejections of claims and the specification

• The rejection of claims 76, 247-254 and 274-279 under 35 USC, 112 second paragraph is now withdrawn in light of cancellation of claim 67 and the applicant's augment regarding claim 81 is persuasive.

• The new matter rejection of claims 46-53, 62, 72, 74, 186-199, 210, 216-228, 239, 241, 245-254, 265, 267, 271 and 280 under 35 USC, 112, first paragraph is withdrawn in light of that the applicants' argument is persuasive

• The rejections of claims 46-49, 62, 72, 74, 186, 192-194, 210, 217, 220-223, 239, 241, 246-249, 265 and 267 under 35 USC 102 by Wuelknitz et al. is withdrawn in light of cancellation of claims 47-48, 62, 72, 74, 192-193, 210, 221-223, 239, 241, 247-249, 265 and 267, and in view of that the applicants' argument is persuasive. The Pall et al. (cited in "Discussion of art" in the Office action mailed 5/23/07) reference describes the dephosphorylation of phosvitin by acid hydrolysis, i.e., the dephosphorylation is resulted from in vitro hydrolysis. Thus, this reference does not support the inherent property that phosvitin isolated from natural source may be dephosphorylated at least 10%.

•The rejection of claims 46-49, 62, 72, 74, 186, 192-194, 210, 217, 219, 221-223, 239, 241, 245, 247-249, 265, 267 and 271-274 under 35 USC 102 by Nakamura et al. is withdrawn in light of cancellation of claims 47-48, 62, 72, 74, 192-193, 210, 216-217, 221-223, 239, 241, 245,

247-249, 265, 267 and 272-274, and in view of that the phosvitin taught by Nakamura et al. is naturally occurring polypeptide and not inherently dephosphorylated at least 10% as isolated.

•The rejection of claim 81 under 35 USC 102 by Pierce in light of that phosvitin taught by this reference is naturally occurring polypeptide and not inherently dephosphorylated at least 10% as isolated.

• Accordingly, the rejection of claims 46-49, 62, 72, 74, 186, 192-194, 210, 217-218, 220-223, 239, 241, 246-249, 265 and 267 under 35 USC 103(a) by Wuelknitz et al. and Shuch et al. is withdrawn in light of the reason set forth above as to the phosphorylation state of the phosvitin, which is not dephosphorylated at least 10%, taught by Wuelknitz et al.

New-Duplicate Claims –Warning

Applicant is advised that should claims 46 and 186 (including the dependent claims thereof) be found allowable, claims 7 and 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

New-Claim objection

Claim 273-279 are canceled (see page 4 of the claim sheets); however, in the same page, applicants clearly set forth the amended claim 273 (still pending). It thus appears that it a typo error for cancellation of claims "273-279.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 46, 49-53, 81, 186, 194-199, 217-220, 246, 272-273, and 280-299 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(*New*) Claims 46, 81, 186 and 272 recites "10% dephosphorylated"; the recitation is unclear as to which standard said percent 10% is compared; does "10%" refer to ten percent of total residues only of Ser and Thr in phosvitin, or/and total residues of Ser, Thr and Tyr wherein said all residues are fully phosphorylate, or "partially phosphorylated" of said residues? Claims which depend from claims 46, 81, 186 and 273 are also rejected.

Claim 281, 287-288 and 294 recitation "...fragment thereof is unphosphorylated" is indefinite becasue it ambiguously refers to (i) the fragment which contains mix of phosphorylated and dephosphorylated Ser or Thr residues but is not further "phosphorylated"; or/and (ii) completely dephosphorylated fragment thereof.

(*Maintained*) Claim 272 recites "attached to"; the recitation is unclear whether or not it refers to an association via non-covalent bond or/and linkage via covalent bond. The Spec at [0167] and [0204] sets forth that "EPACs adhered to, adsorbed onto, bound to, attached to..."; it appears that "*attached to*" lacks clear metes and bounds; does it refers to "adhered to", "adsorbed onto" or/and "bound to" thereof? The Spec does not provide clear definition or meaning thereof. Claim 273 which depends from claim 272 is also rejected because claim 273 does not cure the defect of claim 272.

The applicant's response to the rejection under 35 USC 112, second paragraph

At page 9, the response filed 11/20/07 argues that "attached to" means covalent binding which sis taught at page 15, lines 21-22, and page 17, lines 16-19 of the Spec. Thus, the response request withdrawal of the rejection. This is found unpersuasive because, at page 15, lines 21-22, and at page 17, lines 16-19, the Spec teaches that PAC can be conjugated to a targeting molecule, and teach that homing molecules can be conjugated to a PAC, respectively; these teachings per se do not describe the metes and bounds of the "attached to". Therefore, the rejection is maintained.

New-Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written description

Claims 46, 49-53, 81, 186, 194-199, 217-220, 246 and 280-299 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention. Disclosure of any combination of

such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

(1) Physical and/or chemical properties:

The instant claims 46 and 186 and dependent claims therefrom are drawn to a pharmaceutical composition comprising a phosvitin "fragment". The Spec fails to describe the composition comprising the phosvitin fragment (genus) which encompasses a large number of peptide/oligopeptide subsequences, e.g., dipeptide (Gln-Ala, see NCBI Sequence Viewer (2008, updated) http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=protein&id=212879, page 1) which cannot be phosphorylated/dephosphorylated, and thus is not phosphate acceptor compound (PAC) as disclosed in the instant Spec. The Spec provides none of representative species to adequately reflect variation within the genus. Thus, applicants are not in possession of the claimed pharmaceutical composition for treating mediated by increased phosphorylation, e.g., inflammatory disease and cancer (see the Spec, page 17, line 25 to page 20, line 26).

(2) Level of skill and knowledge in the art/ method of making the claimed invention:

The general knowledge and level of skill in the art do not supplement the omitted description with respect to variant species which are representative of the genus discussed above. The phosvitin is resistant to fragmentation by proteolysis (US Pat. No. 5665868), it may be partially cleaved by partial dephosphorylation and subsequent hydrolysis by trypsin (Xu et al. (2007) *J. Sci. Food Agri.*, 87(14) 2604-2608). Thus, the level of skill and knowledge in the art is high, and thus, written description requires more than a mere statement that it is part of the invention.

(3) Partial structure

The claimed composition is directed to the "phosvitin fragment" which is partial structure of intact phosvitin polypeptide. As discussed above, the Spec fails to describe representative species or examples for the genus "fragment", and fails to teach correlation between structure and function. The phosphorylation state of the phosvitin or fragment thereof is crucial for the function, e.g., reducing the amount of ATP and phosphate groups for phosphorylating the target proteins; thereby inhibiting the unwanted increased phosphorylation (see the instant Spec, page 3, lines 8-12) this underlies the treatment of the disease (see above). Therefore, Applicants did not describe the claimed pharmaceutical composition sufficiently to show they had possession of the claimed genus of "fragment" of phosvitin and the pharmaceutical compositions comprising the "fragment" thereof.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Scope enablement

Claims 49-53, 81, 186, 194-199, 217-220, 246 and 280-299 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of the

pharmaceutical composition comprising phosvitin, does not reasonably provide enablement for the pharmaceutical composition comprising phosvitin fragment, and for that phosvitin can be dephosphorylated to 90% or 100%. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546(BPAI 1986). They include the nature of the invention, the state of the art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

(1) The scope of the claims/(2) The nature of the invention:

Claims 46 and 186 and dependent claims as written are broadly drawn to a pharmaceutical composition comprising a phosvitin "fragment" (genus) which encompasses a large number of subsequences including di- or tri-peptide of the phosvitin polypeptide such as Gln-Ala which cannot be phosphorylated, i.e., Gln-Ala dipeptide is not phosphate acceptor compound (PAC) as described in the instant Spec. The Spec fails to teach correlation of the "fragment" structure with pharmaceutical function thereof. The Spec sets forth that the pharmaceutical composition is useful for treating mediated by increased phosphorylation, e.g., inflammatory disease and cancer (page 17, line 25 to page 20, line 26). The Spec. however does not teach or provide representative example (species) of the "fragment" to enable the claimed

composition. Therefore, the scope of the claimed methods is outside the bounds of the enablement.

Also, the instant disclosure does not enable for "at least 50% dephosphorylation" (claims 51, 197, 284 and 291); "at least 70% dephosphorylation" (claims 52, 198, 285 and 292); and "at least 90% dephosphorylation" (claims 53, 199, 286 and 293); and "unphosphorylated" [equivalent to "100% dephosphorylation] (claims 281, 287-288 and 294). This is becasue neither the Spec nor the relative art teaches that native phosvitin can be dephosphorylated to 50%, 70%, 90% or 100% (unphosphorylated). The art in this field teaches that maximal dephosphorylation of phosvitin is about 40%, and that the reaction of phosphatase with phosvitin from 20 hours to 40 hours shows no further dephosphorylation (see page 2991, Table II, Kato et al. (*Agric. Biol. Chem.* (1987) 51, 2989-2994).

(2) The unpredictability of the art:

Since neither the Spec nor the relative art teaches the composition comprising any fragments encompassing dipeptide and tripeptide or random subsequences of the phosvitin polypeptide suitable for treating the disease discussed above, and since neither the Spec nor the relative art teaches over 50% dephosphorylation of phosvitin (see above), the unpredictability of the art is high.

The state of the prior art/ The amount of direction/guidance disclosed in the Spec:

The art teaches maximal dephosphorylation of phosvitin is 40% not 50%, 70%, 90% or 100% (see Kato et al. reference discussed above), indicating that in some fragments of phosvitin, dephosphorylation cannot be completed. The general knowledge and level of skilled in the art do

not supplement the omitted direction/guidance regarding said dephosphorylation (over 40%) of the fragments, and the pharmaceutical composition comprising the fragment thereof.

(3) The relative skill of those in the art:

The level of skill in this art does not allow the skilled artisan to prepare certain percent of dephosphorylated phosvitin without undue experimentation. This is because phosvitin is resistant to proteolytic fragmentation (US Pat. No. 5665868), and partial dephosphorylation may be required for enzymatical cleavage of phosvitin (see Xu et al. reference). Because the generated proteolytic fragments may be or may not contain fully phosphorylated (at Ser/Thr residues) or partially dephosphorylated, identifying/characterizing certain percent (e.g., 10%, claim 46) dephosphorylation state thereof requires undue level of experimentation which exceeds routine experimentation, and requires at least a molecular biologist with several years of experience in polymer chemistry and peptide synthesis as well as knowledge in toxicology and biochemistry.

(4) The quantity of experimentation necessary:

In the absence of working examples and/or teachings with regard to using the variant peptide compound to treat vascular endothelial tissue damage, it would take undue trials and errors to practice the claimed invention. Because of the above discussed unpredictability, screening for and characterizing numerous species of the "fragment" having been dephosphorylated 50%, 70%, 90% or/and 100% thus require a large quantity of experimentation.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view of the quantity of experimentation necessary, the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and

the breadth of the claims, it would take undue trials and errors to practice the claimed invention. Thus, the amount and level of experimentation needed is undue.

New-Claim Rejections - 35 USC §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

• Claims 46, 49-51, 81, 186, 194-197, 219-220, 246, 280, 282-284, 289-291, 295, and 297-299 are rejected under 35 U.S.C. 102(b) as being unpatentable over Wuelknitz et al. (US Pat. No. 5279814) in view of Jiang et al. (*J. Agric. Food Chem.* (2000) 48, 990-994).

In patent claims 1-2, Wuelknitz et al. teach a dental composition comprising phosvitin wherein said dental composition is in form of a toothpaste or a gel (patent claim 2) or tooth cream or powder (col. 1, line 57), which is non-aqueous solution, as applied to claims 46, 186, 219-220, 246, and 297-299.

Since claim 295 recitation "for topical administration to the skin of an animal" is considered to be an intended use for the pharmaceutical composition which has little patentable weight, claim 295 is included in the rejection.

The phosvitin is obtained from SIGMA (see col. 5, line 47) which is prepared from chicken egg yolk (see "*Discussion of art*" in the Office action mailed 5/23/07), as applied to claims 49 and 194.

Yet, Wuelknitz et al. do not expressly teach or suggest that the phosvitin or fragment thereof is about 10%, or 35% or 50% dephosphorylated.

Jiang et al. teach that although gradual decrease of solubility as hydrophilic phosphate groups of phosvitin were removed, i.e., dephosphorylated, the tryptic fragment of phosvitin ("phosphopeptide, i.e., "PPP") has ability of inhibiting formation of insoluble calcium phosphate (page 993, Fig. 5 and abstract) wherein said "PPP" with 35% phosphate retention, i.e., 65% dephosphorylation, shows calcium solubilization capacity from phosphate precipitate (page 994, left column, 1st paragraph), and teach that this capacity provides the "PPP" as nutraceutical (page 994, left column, last sentence). The Jiang et al. teachings are applied to claim 46 and 186 and claims 50-51, 195-197, 280, 282-284 and 289-291.

Since the kit of claim 81 comprises instruction for using the kit thereof wherein said instruction is considered to have no patentable weight given by its own, and container holding the composition is obvious to any skilled artisan, and since the instruction or/and the container will not alter the structure of the claimed "pharmaceutical composition. See *In re Haller,* 73 USPQ 403 (CCPA 1946), the Court held that an old compound, packaged and labeled to show its use, is not patentable. The packaging of a known compound and the application of an appropriate label thereto does not involved invention over the known compound. Therefore, claim 81 is rejected.

It would have been obvious to one ordinary skill in the art at the time the invention was made to prepared the pharmaceutical composition such as the tooth powders, tooth gels, tooth creams or toothpastes according to Wuelknitz et al. patent, wherein the composition comprises the phosvitin fragment about 65% dephosphorylated. This is because Jiang et al. have taught that

the 65% dephosphorylated (equal to 35% phosphate retained) phosvitin fragment has the highest calcium solubility (see Figure 5) compared to 35% (65% phosphate retention, 82.5% (17.5% phosphate retention) dephosphorylation, i.e., "PPP" with 65% dephosphorylation, has ability of inhibiting the formation insoluble calcium phosphate, and that such the dephosphorylated 'PPP" is useful for be formulated as "nutraceutical" (see above). Thus, in order to eliminate or reduce formation of the insoluble disused above, one skilled in the art would have dephosphorylated phosvitin to ~ 65% followed by tryptic fragmentation of the dephosphorylated phosvitin according to Jiang et al. (see "*Materials and Methods*" section, pages 991), and would have substituted the prepared 65% dephosphorylated "PPP" of phosvitin for the intact phosvitin obtained from SIGMA (see Table 1, "Application Examples") and formulate it into the dental/pharmaceutical composition (as the composition contain calcium) with reasonable expectation of success.

• Claims 218 and 296 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wuelknitz et al. (US Pat. No. 5279814) in view of Jiang et al. (*J. Agric. Food Chem.* (2000) 48, 990-994) as applied to claims 186 and 194, and further in view of Shuch et al. US Pat. No. 6503483).

See the rejection of claims 186 and 194 above.

Yet, neither Wuelknitz et al. nor Jiang et al. expressly teaches that the composition is formulated as drops (claim 218).

Wuelknitz et al. teach the dental formulation (col. 1, lines 55-58). Shuch et al. teach a dental formulation comprising the active component in drops form (see patent claim 19) for oral administration, as applied to claim 218 and 296.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate said composition as drops because drops refer to small quantity of the formulation of claims 218 or/and 296. It would have been within ordinary knowledge and skillfulness of artisan to choose suitable formulation for a particular administration purpose, e.g., formulation as drops for oral administration, as taught by Shuch et al. with reasonable expectation of success. Therefore, it was thus *prima facie* obvious to make and use the dental composition formulated in a special form, e.g., drops.

Conclusion

No claims are allowed.

Discussion of the art

The prior art made of record and not currently relied upon in any rejections is considered pertinent to Applicants' disclosure:

(1) Platt et al. (*Eur. J. Biochem.* (1988) 176, 61-67) teach that dephosphorylation of phosvitin, and the product of the dephosphorylated phosvitin id dissolved in Tris/maleate buffer, pH 6.0 which is not considered to be the pharmaceutical composition. Further, this reference does not teach/suggest percent of the dephosphorylation thereof. Hence, Platt et al. reference is not considered to be the prior art.

(2) Queiroz-Claret et al. (*Nahrung* (1998) 42, 166-167) teach the dephosphorylated (~ 35% after 17 hour reaction with phosphatase) phosvitin in an aqueous solution (page 166). This reference is not considered to be a prior art, because the solution: 0.1 M Tris-HCl buffer, pH8 and 0.5 M NaCl is an aqueous solution which does not meet the limitation of instant claims 46, , 81, 186 and 272 which requires the pharmaceutical composition is not an aqueous solution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon, can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval IPAIRI system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAG only. For more information about the PAN system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Samuel W Liu/
Examiner, Art Unit 1656

February 19, 2008

/Karen Cochrane Carlson, Ph.D./
Primary Examiner, Art Unit 1656